TRANSVENOUS VERSUS TRANSTHORACIC CARDIOVERTER-DEFIBRILLATOR IMPLANTATION

A comparative analysis of morbidity, mortality, and survival

The hypothesis that transvenous implantation of a cardioverter-defibrillator is associated with less morbidity than use of a transthoracic approach was investigated in a retrospective series of 146 patients. None of these patients had concomitant heart procedures, and the preoperative characteristics of the two groups were similar. When analyzed by actual technique used (transvenous, 57 patients; transthoracic, 89 patients) and by the intention-to-treat method (transvenous, 65 patients, 8 of whom actually underwent thoracotomy; thoracotomy, 81 patients), transvenous implantation was associated with a lower incidence of postoperative respiratory complications and atrial fibrillation. Total cardiac mortality and freedom from sudden cardiac death in the transvenous and transthoracic groups were comparable at 2 years. (J THORAC CARDIOVASC SURG 1995;109:1066-74)

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Until recently, placement of an implantable cardioverter-defibrillator (ICD) system required a major operative procedure, which was performed through a left thoracotomy, sternotomy, or subxiphoid approach. The morbidity and mortality rates associated with this procedure, although lower than might be expected considering the degree of cardiac dysfunction of most ICD recipients, are still significant.[1-4] Furthermore, some authors have suggested that complications of ICD implantation have been reported with less rigor than those of other surgical procedures.[3]

In an attempt to reduce the perioperative morbidity and mortality of ICD implantation, as well as the associated length of hospitalization and total cost, endocardial lead systems have been developed that do not require thoracotomy. We present our initial experience with 57 such transvenous implants performed at our institution (group A) and compare them with 89 implantations performed via a sternotomy or thoracotomy (group B). These two groups were subjected to a rigorous analysis of perioperative morbidity and mortality in an attempt to assess relative safety. This analysis was carried out first with the *actual technique* used (A1 versus B1) and then on an *intention-to-treat* basis (A2 versus B2).

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Material and methods

The records of all 146 consecutive patients who underwent placement of a complete ICD system were reviewed. Twenty-seven contemporaneous patients who underwent ICD implantation associated with coronary bypass or valvular procedures were excluded from analysis because such procedures would potentially prejudice the transthoracic group. The preoperative demographic characteristics, intraoperative electrophysiologic findings, perioperative morbidity and mortality, and discharge data were examined.

Statistical analysis. Discrete variables were compared by Miettinen's modification of Fisher's exact test or the Yates corrected χ^2 statistic. Continuous variables were compared by Student's t test or the Mann-Whitney test.

Perioperative mortality was defined as any death that occurred in the hospital or any death that occurred at home within 30 days of ICD implantation unless clearly unrelated to the procedure. One patient in the transvenous group died at home of a documented bradyarrhythmia 27 days after implantation. This death was regarded as unrelated to the operative procedure and was listed as a late rather than a perioperative death. However, the analysis was also repeated with this patient listed with those who had perioperative death.

Morbidity and mortality data were analyzed in two different ways. First, the 57 patients who actually underwent transvenous placement (group A1) were compared with 89 patients who ultimately underwent transthoracic placement (group B1). However, eight patients in group B1 had undergone an initial unsuccessful attempt at transvenous placement, which could unfairly prejudice the

rates of perioperative morbidity and mortality in this group (such cases were longer and required more arrhythmia inductions). Accordingly, the morbidity data were reanalyzed with use of an intention-to-treat principle. The 65 patients who underwent attempted transvenous placement, even if the procedure failed and a thoracotomy was required, were placed in the transvenous group (group A2). They were compared with 81 patients (group B2) who underwent thoracotomy as the planned procedure and in whom transvenous placement was not attempted.

Logistic regression analysis was performed with multiple preoperative characteristics (age, sex, cause of disease, clinical presentation, history of myocardial infarction, extent of coronary artery disease, severity of angina, cardiac failure, unrevascularized coronary artery disease, and operative approach) as independent variables and postoperative length of stay less than or equal to 9 days or more than 9 days (our median value) as the binary dependent variable. This was believed to be the best overall indicator of postoperative morbidity.

Survival analysis was done by the Kaplan-Meier method. Total cardiac mortality included all cardiac deaths (operative, nonsudden, and sudden) but excluded noncardiac deaths. Sudden cardiac deaths included unwitnessed deaths and those that occurred within 1 hour of onset of symptoms. Comparison between groups was performed with the Tarone-Ware test.

Surgical techniques

General. Patients with coronary disease usually underwent objective testing for myocardial ischemia. Exceptions to this rule included patients whose conditions were too clinically unstable or patients whose absence of angina or profound left ventricular dysfunction made them unlikely candidates for revascularization. Coronary angiography was performed when appropriate to determine the need for concomitant bypass (a patient requiring such operation was excluded from this study). The ejection fraction was determined by single-plane right anterior oblique contrast ventriculography, two-dimensional echocardiography, or radionuclide ventriculography. All but three of the patients underwent extensive preoperative electrophysiologic testing. One of these patients had incessant, unprovoked ventricular tachycardia that was pace terminable, one patient had severe left main coronary artery disease, and one patient, after out-of-hospital cardiac arrest, did not undergo testing because arrhythmia had been noninducible on multiple previous electrophysiologic studies.

Perioperative intraaortic balloon counterpulsation was used for some patients with severe left ventricular dysfunction, unrevascularized coronary artery disease, or both conditions. Patients with perioperative balloon pumps had counterpulsation discontinued just before induction of each episode of arrhythmia, and the device was reactivated immediately after successful termination of the arrhythmia.

All patients underwent operation with continuous monitoring of pulmonary artery and central venous pressures, arterial pressure, and, most recently, continuous mixed venous oxygen saturation monitoring. Cardioversion and defibrillation threshold testing were initiated at 15 joules and continued according to a "step protocol." A 10-joule buffer between the determined defibrillation threshold testing and the maximum output of the ICD generator was required. ICD generators were placed in a subrectus fascia pocket in the left side of the abdomen.

After operation, patients received intravenous lidocaine (Xylocaine) for 24 hours. The ICD generator was activated as soon as possible after operation, usually in the operating room. The patients underwent testing in the electrophysiologic laboratory before discharge from the hospital to confirm appropriate ICD function and were subsequently followed up in an ICD clinic every 2 months.

Thoracotomy. Choice of a sternotomy or left thoracotomy was based on several factors. Sternotomy was generally restricted to patients who had severe preoperative pulmonary dysfunction. A left anterior thoracotomy was used for most other patients. Extrapericardial placement of two large patches was used whenever possible with multipoint fixation of the patches to the pericardium after removal of the overlying fat. Patches were oriented in a longitudinal direction. Bipolar screw electrodes were placed in a viable portion of myocardium anteroapically or high on the left lateral wall. An attempt was made to remove chest tubes as early as possible in the postoperative course, typically on postoperative day 1, to prevent contamination of the pleural space.

Transvenous placement. Patients scheduled to receive transvenous ICD units were positioned on the operating table with a small roll under the left side of the chest to provide access for emergency anterior thoracotomy. A generator pocket was created in the left side of the abdomen, and a short cephalic venous cutdown was performed. The defibrillator lead system (Endotak, Cardiac Pacemakers, Inc. [CPI], St. Paul, Minn.) consists of proximal and distal spring coils for defibrillation. Three sizes are available, with 10, 13, or 16 cm spacing between the proximal and distal electrodes. The proximal electrode was positioned under fluoroscopic control at the right atrial–superior vena cava junction, with the tip of the electrode placed at the right ventricular apex. It has been our subjective impression that the optimal position is adjacent to the septum. The Endotak system lead tip also has a bipolar rate-sensing and pacing electrode.

A subcutaneous patch electrode, which is similar to the epicardial patch electrode used for transthoracic implantation, was used in some patients. Four configurations are available using the electrode and patch: these were used in randomized fashion as part of a clinical trial during the series presented. In configuration 1, the subcutaneous patch is the anode and the proximal and distal endocardial leads the cathode. In configuration 2, the patch and proximal shocking electrode are the anode and the distal shocking electrode is the cathode. In configuration 4, the distal shocking electrode is the cathode and the subcutaneous patch is the anode. Finally, in configuration 3, the proximal shocking electrode is the anode and the distal shocking electrode is the cathode. Four additional configurations may be obtained by reversing these polarities. Comparable configurations may be obtained with use of a subcutaneous array rather than the patch.

The Endotak system lead was doubly anchored (with the sleeves provided) within the cephalic pocket and then tunneled subcutaneously to the abdominal pocket, where testing was performed. When a patch was used, a subcu-

Table I. *Demographics*

	Group A1: transvenous (n = 57)	*Group B1: transthoracic (n = 89)*	*p Value*
Age in years (median)	68 (23-80)	65 (31-83)	0.4432
Sex			
Male	46 (80.7%)	72 (80.9%)	
Female	11 (19.3%)	17 (19.1%)	1.0000
Arrhythmia presentation			
Syncope	18 (31.6%)	31 (34.8%)	
Arrest	23 (40.4%)	34 (38.2%)	0.9203
Ventricular tachycardia	16 (28.1%)	24 (27.0%)	
Cause*			
Ischemia	47 (82.5%)	68 (76.4%)	
Idiopathic	5 (8.8%)	15 (16.9%)	
Hypertrophic cardiomyopathy	1 (1.8%)	4 (4.5%)	0.2808
Valvular	3 (5.3%)	2 (2.3%)	
Congenital	1 (1.8%)	0	
Previous myocardial infarction	49 (86.0%)	64 (71.9%)	0.0713
Previous cardiovascular operation	28 (49.1%)	28 (31.5%)	0.0497
Extent of coronary artery disease			
Three vessel or left main	22 (38.6%)	26 (29.2%)	0.3189
Angina†			
None	45/56 (80.4%)	69/84 (82.1%)	
Mild	7/56 (12.5%)	14/84 (16.7%)	0.1545
Moderate	4/56 (7.1%)	1/84 (1.2%)	
Severe	0	0	
Thallium testing			
Negative results	15 (26.3%)	21 (23.6%)	
Positive results	9 (15.8%)	11 (12.4%)	0.7350
Not performed	33 (57.9%)	57 (64.0%)	
Ejection fraction (%, mean)	31.9 ± 15.3	31.3 ± 15.2	0.8026
Left ventricular aneurysm	13 (22.8%)	13 (14.6%)	0.2978
Unrevascularized coronary artery disease	31 (54.4%)	57 (64.0%)	0.3221
Preoperative intraaortic balloon pump	6 (10.5%)	26 (29.2%)	0.0114

*Causes other than ischemic grouped together for statistical analysis.
†Only 56 patients in group A and 84 patients in group B available for analysis.

taneous pocket was created at the level of the left ventricular apex and secured with stitches. This lead was also tunneled into the abdominal pocket.

At the completion of a successful procedure, the Swan-Ganz catheter (Baxter Healthcare Corp., Edwards Div., Santa Ana, Calif.) was removed under fluoroscopic control, with care taken not to dislodge the Endotak system lead during withdrawal. Immediate postoperative roentgenography provided a baseline reference for lead position. Patients were kept immobile for 24 hours after operation and were encouraged to restrict movement of the left arm temporarily. Lead position was reconfirmed by roentgenography of the chest before the patient was discharged from the hospital.

Results

Preoperative demographics are reviewed in Table I. Eighty percent of patients in both groups were men in the seventh decade of life. Seventy percent of patients had had a cardiac arrest or syncopal episode caused by malignant ventricular arrhythmia, and the remainder had had repetitive sustained ventricular tachycardia. Ischemic heart disease was the cause of the malignant ventricular arrhythmia in 80% of patients in both groups. More than 50% of patients had some unrevascularized coronary artery disease, although the difference was not significant between the two groups. Usually, this unrevascularized coronary artery disease was an anatomic finding only. Of the 88 patients in both groups who had some unrevascularized coronary artery disease, 78 patients (88.6%) were completely free of symptoms or had only mild angina and 61 patients (69.3%) had only one- or two-vessel coronary artery disease. The remainder of the patients with unrevascularized coronary artery disease had poor operative targets

or, in one case, eggshell calcification of the ascending aorta that precluded safe revascularization. Patients with objective or subjective evidence of ischemia usually underwent concomitant bypass operation and were excluded from this study.

Twenty-six patients had left ventricular aneurysms that were not repaired. In all instances, these aneurysms were either small and asymptomatic (except as a possible arrhythmogenic focus) or were associated with profound dysfunction of the nonaneurysmal segments.

The mean ejection fraction in the two groups was identical at 31%. Forty-nine percent of group A patients had previous cardiovascular operation compared with 31.5% in group B, which was a statistically significant difference ($p = 0.0497$). In group A, 10.5% of patients underwent perioperative intraaortic balloon counterpulsation support compared with 29.2% in group B ($p = 0.0114$). This reflects our subjective impression that transvenous insertion is better tolerated and that even critically ill patients can undergo the procedure without balloon pump support.

The higher incidence of patients in the transvenous group who had a previous cardiovascular operation reflected our desire to avoid repeat thoracotomy in those patients.

No significant difference was detected in defibrillation thresholds between the two groups (transvenous, 14.9 ± 5.1 joules; transthoracic, 13.3 ± 5.2 joules; $p = 0.0846$). Lead impedance was significantly lower in the thoracotomy group (group A, 46.8 ± 7.0 ohms; group B, 37.6 ± 6.1 ohms; $p < 0.0001$).

Seventy-nine (88.8%) of 89 transthoracic procedures were performed through a limited left thoracotomy and the remainder by way of sternotomy. Two extrapericardial patches were used in 85 patients (95.5%), and both patches were the large size in 73 patients (82.0%). For transvenous placement, the most common configuration was "lead only" (42 patients, 73.7%), with the use of either normal (33 patients, 57.9%) or reverse (9 patients, 15.8%) polarity.

The median time from operation to hospital discharge was 6.0 days in the transvenous group and 9.0 days in the thoracotomy group ($p < 0.0001$). Calculated on an intent-to-treat basis, the corresponding values were 6.0 and 10.0 days ($p < 0.0001$).

The perioperative rates of morbidity and mortality by actual approach used are compared in Table II. No deaths occurred in 57 patients in the transvenous group and 2 deaths occurred in the thoracotomy group, although the difference was not statistically significant. The mortality data were also recalculated including in the group of patients with perioperative death the patient who died at home 27 days after operation (of what was believed to be a preexisting bradyarrhythmia). Again, no difference in mortality existed between the two groups either by the actual (1 of 57 versus 2 of 89, $p = 0.8864$) or intention-to-treat (1 of 65 versus 2 of 81, $p = 0.7504$) methods. No difference was seen in perioperative myocardial infarction, the occurrence of ventricular arrhythmias, or congestive heart failure after operation. More patients in the thoracotomy group required postoperative inotropic support (two of whom also required intraaortic balloon pumps), but the difference was not statistically significant. A highly significant increase was noted in the incidence of postoperative atrial fibrillation in the thoracotomy group: 28% compared with 8.8% for the transvenous group ($p = 0.0042$).

Pulmonary complications were significantly reduced with the transvenous approach, with a prevalence of atelectasis or lobar collapse of 21.4% in the thoracotomy group and 1.8% in the transvenous group ($p = 0.0007$). A higher proportion of patients in the transvenous group had no respiratory complications whatsoever (93% versus 66%, $p = 0.0001$).

These data on morbidity and mortality were then recalculated with use of the intention-to-treat principle (Table III). The prevalence of atrial fibrillation was still increased nearly threefold in the thoracotomy group compared with that in the transvenous group (28.4% versus 10.8%, $p = 0.0139$). The incidence of atelectasis and lobar collapse in the transthoracic group was more than twice that of the transvenous group, although the p value did not attain statistical significance (18.5% versus 7.7%, $p = 0.0950$). Eighty-six percent of patients who underwent the transvenous approach had no complications whatsoever compared with 69% of the transthoracic group ($p = 0.0160$).

Logistic regression analysis was performed with data from the 140 patients for whom data were complete for all variables. Stepwise forward regression revealed that only transthoracic operative approach correlated with prolonged postoperative hospital length of stay (coefficient, 0.8026; coefficient/standard error, 3.78; relative risk, 2.22; 95% confidence limits 0.46, 10.76).

Total cardiac survival and freedom from sudden

Table II. *Complications by actual approach*

	Group A1: transvenous (n = 57)		*Group B1: transthoracic (n = 89)*		
	No.	*%*	*No.*	*%*	*p Value*
Death	0		2	2.3	0.7400
Cardiac complications					
Myocardial infarction	5	8.8	8	9.0	1.0000
Inotropic support	1	1.8	8	9.0	0.1443
Ventricular tachycardia/ventricular fibrillation	7	12.3	9	10.1	0.8787
Atrial fibrillation	5	8.8	25	28.1	0.0042
Congestive heart failure	5	8.8	8	9.0	1.0000
Heart block	1	1.8	0		0.7808
Tamponade	0		1	1.1	1.0000
No cardiac complications	38	66.7	53	59.6	0.3945
Pulmonary complications					
Adult respiratory distress syndrome	0		1	1.1	1.0000
Pneumonia/bronchitis	2	3.5	4	4.5	0.8077
Atelectasis/lobar collapse	1	1.8	19	21.4	0.0007
Prolonged intubation	1	1.8	7	7.9	0.2200
Pulmonary embolism	0		1	1.1	1.0000
No respiratory complications	53	93.0	59	66.3	0.0001
Surgical complications					
Revision, same admission	1	1.8	1	1.1	1.0000
Hemothorax necessitating chest tube or thoracentesis	0		4	4.5	0.2688
Hemothorax (reoperation)	0		0		
Pneumothorax	1	1.8	1	1.1	1.0000
Prolonged air leak	1	1.8	1	1.1	1.0000
Retroperitoneal hematoma	2	3.5	0		0.3016
Generator seroma, hematoma, erythema (no surgical treatment)	5	8.8	2	2.3	0.1641
Generator hematoma, drain	2	3.5	0		0.3016
Generator hematoma, explant	0		1	1.1	1.0000
Generator erosion	0		1	1.1	1.0000
Coronary vessel erosion	0		1	1.1	1.0000
Intraaortic balloon pump vascular injury	0		3	3.4	0.4500
General complications					
Neurologic	0		1	1.1	1.0000
Urinary tract infection	0		6	6.7	0.0959
Urinary retention	1	1.8	3	3.4	0.9816
Upper gastrointestinal tract bleeding	1	1.8	1	1.1	1.0000
Superior vena cava thrombosis	0		1	1.1	1.0000
Cholecystitis	0		1	1.1	1.0000
Acute tubular necrosis	0		2	2.3	0.7400
Ileus	2	3.5	1	1.1	0.6743

cardiac death were compared. No statistically significant differences were seen at 2 years (Figs. 1 and 2).

Discussion

The introduction of the ICD has greatly diminished the risk of sudden cardiac death in patients with malignant ventricular arrhythmias. In most large series, the operative mortality rate has ranged from 1.5% to 4%.[1-5] Despite some lack of consistency in the reporting of ICD complications,[3] significant perioperative morbidity can occur.

A nonthoracotomy approach has been developed in an attempt to avoid thoracotomy and reduce perioperative morbidity, length of hospital stay, and cost. Potential problems with this approach include the inability to pass a lead into the appropriate position, inadequate defibrillation thresholds necessitating conversion to thoracotomy, lead migration,

Table III. *Complications by intention-to-treat*

	Group A2: transvenous (n = 65)		*Group B2: transthoracic (n = 81)*		
	No.	*%*	*No.*	*%*	*p Value*
Death	0		2	2.5	0.5759
Cardiac complications					
Myocardial infarction	8	12.3	5	6.2	0.3169
Inotropic support	3	4.6	6	7.4	0.7357
Ventricular tachycardia/ventricular fibrillation	8	12.3	8	9.9	0.8357
Atrial fibrillation	7	10.8	23	28.4	0.0139
Congestive heart failure	7	10.8	6	7.4	0.6731
Heart block	1	1.5	0		0.8904
Tamponade	0		1	1.2	0.5548
No cardiac complications	42	64.6	49	60.5	0.6157
Pulmonary complications					
Adult respiratory distress syndrome	0		1	1.2	0.5548
Pneumonia/bronchitis	2	3.1	4	4.9	0.8992
Atelectasis/lobar collapse	5	7.7	15	18.5	0.0950
Prolonged intubation	2	3.1	6	7.4	0.4431
Pulmonary embolism	0		1	1.2	0.5548
No respiratory complications	56	86.2	56	69.1	0.0160
Surgical complications					
Revision, same admission	1	1.5	1	1.2	1.0000
Hemothorax necessitating chest tube or thoracentesis	0		4	4.9	0.1832
Hemothorax (reoperation)	0		0		
Pneumothorax	1	1.5	1	1.2	1.0000
Prolonged air leak	1	1.5	1	1.2	1.0000
Retroperitoneal hematoma	2	3.1	0		0.3825
Generator seroma, hematoma, erythema (no surgical treatment)	5	7.7	2	2.5	0.2817
Generator hematoma, drain	2	3.1	0		0.3825
Generator hematoma, explant	0		1	1.2	0.5548
Generator erosion	0		1	1.2	0.5548
Coronary vessel erosion	0		1	1.2	0.5548
Intraaortic balloon pump vascular injury	0		3	3.7	0.3267
General complications					
Neurologic	0		1	1.2	0.5548
Urinary tract infection	0		6	7.4	0.0535
Urinary retention	1	1.5	3	3.7	0.7938
Upper gastrointestinal tract bleeding	1	1.5	1	1.2	1.0000
Superior vena cava thrombosis	0		1	1.2	0.5548
Cholecystitis	0		1	1.2	0.5548
Acute tubular necrosis	0		2	2.5	0.5759
Ileus	2	3.1	1	1.2	0.8470

lead fracture (which resulted in abandonment of the first-generation endocardial system), subclavian vein thrombosis, pneumothorax, and ventricular free wall or ventricular septal perforation.[6]

The initial clinical trials of the second-generation lead system (CPI Endotak) used in our study began in September 1990. Another transvenous device manufactured by Medtronic, Inc. (Minneapolis, Minn.) has also undergone clinical trials.

The results of several institutional and combined study groups are now available. Hauser and associates[7] have reported on 292 epicardial implantations performed in comparison with 298 transvenous implants in a multiinstitutional study. The postoperative mortality rate was 1.3% in the transvenous group and 2.7% in the epicardial group (p value not significant), and the frequency of complications reported for each group was similar. However, 18%

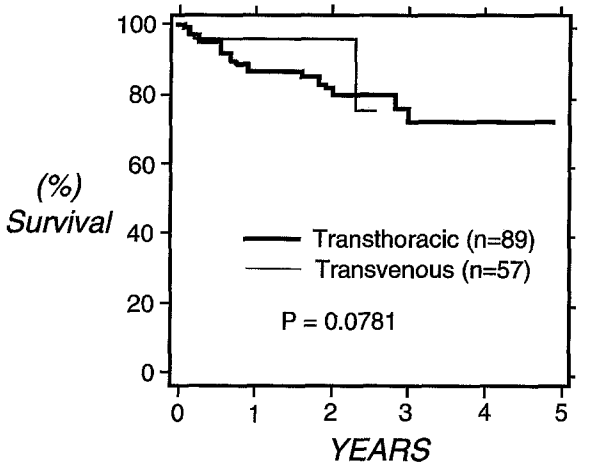

Fig. 1. Comparison of freedom from all cardiac causes of death in transvenous and transthoracic groups. No significant difference is seen at 2 years.

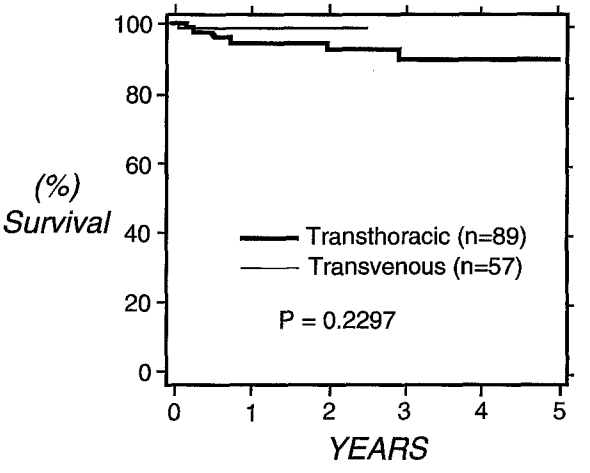

Fig. 2. Comparison of freedom from sudden cardiac death in transvenous and transthoracic groups. No significant difference is seen at 2 years.

of patients in the transthoracic group underwent concomitant heart operations, cryoablation, or pacemaker insertion procedures, none of which were performed in the endocardial group.

Frame and associates[8] reported on 34 patients who underwent attempted transvenous lead implantation with the Medtronic system with an 88.2% success rate (30 implants). In their entire series of 105 patients, including transthoracic procedures, the overall operative mortality rate was 3.8%. None of the patients who received a transvenous system died in the postoperative period, but the perioperative morbidity and operative time were increased.

Saksena and the Medtronic PCD Investigator Group[9] reported on a multiinstitutional study of 616 patients who underwent epicardial ICD placement who were compared with 605 patients who had an endocardial system. Implantation mortality was lower in the endocardial group by either actual or intention-to-treat analysis, although a detailed review of complications was not reported. Survival analysis revealed an advantage for the endocardial system at 2 years but only when operative mortality was excluded. A major flaw with this study was the inclusion of patients who underwent concomitant cardiac operation (14.6%) in the epicardial group, which probably had a significant adverse impact on the perioperative mortality.

In an initial study by Böcker and associates,[10] among 107 patients who underwent transvenous ICD placement with both CPI and Medtronic devices, successful implantation was achieved in 99 patients (92.5%). Although the surgical mortality rate for the transvenous group was low (1%), statistical comparison of perioperative morbidity and mortality between transvenous and transthoracic groups was not performed.

Trappe and associates[11] described their initial experience with a CPI Endotak lead system in 47 patients, with successful implantation in 39 patients (83%). The operative mortality rate was high (5%), no detailed analysis of morbidity was provided, and no comparison was made with a comparable transthoracic group.

Bardy and associates[12] reported a 95% success rate with the Medtronic device in their initial experience with 84 patients who underwent attempted transvenous lead insertion. They reported an absence of postoperative pulmonary complications and arrhythmias in the transvenous group. However, other significant postoperative complications included eight lead dislodgments (10%), two subclavian vein occlusions, one pulse generator pocket infection, and one lead fracture.

Two additional abstracts have used the intention-to-treat principle to compare transvenous and epicardial ICD systems. Kleman and associates[13] compared 90 patients in whom the initial implant approach was transvenous with 67 comparable patients in whom the approach was epicardial. Seventy-six (84.4%) of the 90 patients actually received a transvenous system. The surgical mortality rate was 2.2% in the transvenous group and 3% in the transthoracic group (p value not significant).

The prevalence of postoperative morbidity, including supraventricular or ventricular arrhythmias, congestive heart failure, and pulmonary complications, did not differ significantly between the groups, and the hospital stay was the same. In a similar intention-to-treat analysis, Lehmann and associates[14] compared 379 patients who were chosen preoperatively to receive a transvenous lead with 401 patients who received transthoracic implants. The transvenous approach was successful in 317 (84%) of 379 patients. Operative mortality was lower for the transvenous group both by intention-to-treat and actual implant analysis. An analysis of complications was not presented in the abstract, and some patients who underwent concomitant heart operations were apparently included in the transthoracic group.

Thus, despite initial trials of a transvenous device in multiple centers in the United States and Europe, few have rigorously compared the transvenous with the transthoracic approach. Such a trial should describe perioperative morbidity and mortality both in terms of actual and intention-to-treat principles and should not be biased against the transthoracic group by the inclusion of patients who have concomitant heart operations. We believe that our single institution trial, with both transvenous and transthoracic procedures performed by the same group of cardiologists and cardiac surgeons, meets these criteria. Our data demonstrate that the transvenous approach results in lower morbidity than the transthoracic approach, even when the intention-to-treat principle is used. Fewer atrial arrhythmias occur because the pericardium is not disturbed, and there is a trend toward a lower prevalence of respiratory complications because a thoracotomy is not needed. Median length of hospital stay after operation is shorter with the transvenous approach, and operative approach was the only variable in multivariate logistic regression analysis that correlated with short versus long length of stay.

Our data concur with those of Böcker and associates,[15] who reported that the prevalence of ventricular arrhythmias did not differ between the two techniques. This finding suggests that ventricular arrhythmias arise not from myocardial irritation by patch electrodes but possibly from an increase in levels of endogenous catecholamines or some other mechanism.

In our experience, a lead-only configuration was used in 73.7% of patients, which is a higher percentage than found in most other series. A reverse configuration was used in 9 of these 42 patients and may obviate the need for a subcutaneous patch. In a nonthoracotomy lead system, it is particularly important to ensure satisfactory defibrillation thresholds after operation because a rise in chronic defibrillation thresholds over time has been demonstrated by Venditti and associates[16] and Hsia, Flores, and Marchlinski.[17]

Only one of our patients had lead migration that necessitated revision during the same hospitalization. This low incidence attests to the importance and efficacy of the maneuvers discussed in the surgical technique section.

Our survival analysis suggests that, at least during short-term follow-up, no difference exists between the transvenous and transthoracic approaches.

In conclusion, transvenous ICD implantation may be achieved with a high rate of success and lower morbidity than that for the transthoracic procedure, and survival is comparable. Subsequent developments in ICD technology, including biphasic shocks and the use of multielectrode subcutaneous arrays, should further increase the likelihood of successful transvenous implantation and reduce the need for thoracotomy.

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